Contents

		Page	
DIGEST		i	1/A7
CHAPTER			
1	INTRODUCTION	1	1/A14
	The chemical industry--a profile	1	1/A14
	Benefits and hazards of chemicals	1	1/A14
	Closing the gaps in environmental legislation	2	1/B1
	Information gathering	4	1/B3
	Screening new chemicals	5	1/B4
	Testing chemicals	6	1/B5
	Chemical control	6	1/B5
	Objectives, scope, and methodology	7	1/B6
2	PROBLEMS CHARTING A COURSE AND DEVELOPING AN ORGANIZATIONAL BASE	8	1/B7
	Organizational and staffing problems hindered implementation	8	1/B7
	Problems developing an organizational structure	8	1/B7
	Problems hiring qualified staff	10	1/B9
	Program direction has been unclear	12	1/B11
	No clear strategic plan was developed to guide program implementation	12	1/B11
	Efforts to develop a planning system	16	1/C1
	Major reorganization: an attempt to correct problems	17	1/C2
	Conclusions	18	1/C3
3	CONTROLLING EXISTING CHEMICALS: A RELATIVELY LOW EPA PRIORITY	19	1/C4
	EPA has been slow to collect basic information	19	1/C4
	The chemical inventory limited to chemical identity and production data	20	1/C5
	Use, exposure, and effects data not obtained	21	1/C6
	Few health and safety studies have been requested	22	1/C7
	Recordkeeping and reporting requirements not fully implemented	23	1/C8

CHAPTER		Page
	EPA has been slow to assess the risks of existing chemicals	24 1/C9
	Procedures for performing assessments are not complete	24 1/C9
	Status of assessments	27 1/C12
	Industry not required to test chemicals	28 1/C13
	Only health effects test standards have been proposed	29 1/C14
	Test rules have not been developed	29 1/C14
	Few control actions have been taken	31 1/D2
	Conclusions	33 1/D4
4	NEW CHEMICALS ARE BEING SCREENED, BUT MORE NEEDS TO BE DONE	35 1/D6
	Requirement for identifying hazardous chemicals before manufacture	35 1/D6
	PMN program needs improvement	36 1/D7
	PMN program operating under interim guidance pending final rules	36 1/D7
	EPA must use all TSCA authority to obtain needed information	37 1/D8
	Need to establish operating procedures and decision criteria	40 1/D11
	Issues which must be resolved	41 1/D12
	Need for information versus impact on industry	41 1/D12
	Protecting confidential business information while at the same time assuring meaningful public disclosure	43 1/D14
	Conclusions	45 1/E2
	Recommendations	46 1/E3
	Agency comments	46 1/E3
APPENDIX		
I	Organizational structure (March 27, 1978, to present)	47 1/E4
II	Proposed reorganizational structure (March 1980)	48 1/E6

APPENDIX Page

III Letter dated September 8, 1980, from the Assistant Administrator for Planning and Management, EPA 49 17E8

ABBREVIATIONS

ANPRM	Advanced Notice of Proposed Rulemaking
CFC	chloroflourocarbon
DAA	deputy assistant administrator
EPA	Environmental Protection Agency
GAO	General Accounting Office
ITC	Interagency Testing Committee
MAC	Management Analysis Center, Inc.
OPAM	Office of Policy Analysis and Management
OPTS	Office of Pesticides and Toxic Substances (formerly the Office of Toxic Substances)
OTE	Office of Testing and Evaluation
OTS	Office of Toxic Substances
PCB	polychlorinated biphenyl
PMN	premanufacture notice
SOLC	Section of Law Committee
TSCA	Toxic Substances Control Act of 1976

546-5

GA1.13: CED-81-1

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

COMPLETED
ORIGINAL

EPA Is Slow To Carry Out Its Responsibility To Control Harmful Chemicals

For almost 4 years EPA has had broad authority to protect the public and the environment from the harmful effects of chemicals. Although actions have been taken to control three chemicals, no chemicals have been tested and basic data is lacking on most of the other 55,000 chemicals now in use. New chemicals are being screened, but implementing regulations and the review process itself have not been completed.

Several factors have contributed to this slow progress, including no clear sense of direction to guide the program, and organizational and staffing problems. EPA is working to resolve these problems.

CED-81-1
OCTOBER 28, 1980

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-199856

To the President of the Senate and the
Speaker of the House of Representatives

In October 1976 the Congress enacted the Toxic Substances Control Act giving the Environmental Protection Agency broad new authority to control chemicals which present an unreasonable risk to health or the environment. Therefore, we made our review to determine the problems the Environmental Protection Agency has faced in implementing this complex act and the corrective actions which have been or are being taken.

Copies of this report are being sent to the Director, Office of Management and Budget; the Chairman, Council on Environmental Quality; and the Administrator, Environmental Protection Agency.

Comptroller General
of the United States

B

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

EPA IS SLOW TO CARRY OUT ITS RESPONSIBILITY TO CONTROL HARMFUL CHEMICALS

D I G E S T

The Toxic Substances Control Act of 1976 gave the Environmental Protection Agency (EPA) a broad mandate to protect the public and the environment from unreasonable chemical risks. However, almost 4 years later, neither the public nor the environment are much better protected.

ORGANIZATIONAL AND STAFFING PROBLEMS SLOWED IMPLEMENTATION

EPA was not prepared to fulfill its new statutory responsibilities when the Toxic Substances Control Act was enacted, and subsequent problems in developing and staffing a new organization have contributed to EPA's slow progress in meeting the objectives of the act. Other factors such as the absence of a clearly articulated plan of action and an ineffective organizational structure have also impeded progress. (See pp. 8 to 12.)

At the same time EPA was establishing an organizational base, it was also working on developing a strategy to guide program implementation. In spite of considerable effort, no formal strategy emerged. Instead, work proceeded without a clear understanding of how it would fit into a comprehensive toxics program. (See pp. 12 to 15.)

EPA recognized the need to make major changes in the program and has taken action. First, it agreed in December 1979 on a basic framework for guiding program activities. Second, it proposed a major reorganization in March 1980 which would consolidate responsibility for conducting the toxics program under one deputy assistant administrator. (See pp. 16 to 18.)

CED-81-1

Tear Sheet. Upon removal, the report cover date should be noted hereon.

EXISTING CHEMICALS

In 1976 there was little basic knowledge of how many chemicals were in commerce, how they were being used, who was being exposed, and which ones were toxic. To remedy this situation, EPA was granted broad authority to gather such information, identify those chemicals which are harmful, and control those which present an unreasonable risk. To date, EPA's progress has been disappointing.

Although compiling a chemical inventory greatly expanded the current data base, EPA has been slow to obtain other information needed to systematically assess the risks posed by the more than 55,000 chemicals already in commerce. Several factors delayed the development of rules to request more information, including limited staff support, time needed to resolve basic issues, and difficulty getting information from the inventory. (See pp. 19 to 24.)

Before EPA can initiate action to control a chemical, it must assess the chemical's risk. However, EPA has placed less emphasis on assessing and controlling existing chemicals than on new chemicals partly because other Federal programs have considerable regulatory authority over existing chemicals. At present, EPA has allotted enough staff and money to initiate only two or three control actions on existing chemicals annually. (See pp. 24 to 28.)

Certain control actions, however, have been completed. Polychlorinated biphenyls have been regulated as required by the act, chloroflourocarbon propellants have been banned in aerosol containers, and the disposal of dioxin wastes has been restricted. In fiscal year 1981 EPA plans to initiate several actions to control asbestos. (See pp. 31 to 34.)

More must be done before EPA will have an effective program to control existing chemicals. Although EPA has developed interim management plans for the assessment process,

it needs a system to set priorities for chemicals so that those presenting the greatest risk are evaluated first. In addition, it must develop criteria to determine the appropriate course of action to take on a chemical as it moves through the assessment process. These are scheduled to be in place by fiscal year 1981, according to EPA. (See pp. 24 and 25.)

In addition to identifying and controlling potentially harmful chemicals, the act requires EPA to initiate action within 180 days of receipt of information indicating that a chemical may cause cancer, gene mutations, or birth defects. Although this requirement became effective January 1, 1979, EPA has not yet developed operational criteria to carry out this requirement because it has been unable to resolve basic issues. However, EPA is now working on a policy statement and operational criteria to implement this requirement. (See pp. 25 to 27.)

NO TESTING HAS BEEN REQUIRED FOR CHEMICALS

In conjunction with EPA's broad mandate to control existing chemicals, the Toxic Substances Control Act established the Interagency Testing Committee to recommend chemicals for priority testing. EPA is required to initiate rulemaking procedures within 1 year to require the testing or to specify its reasons for not doing so.

EPA has not required the testing of any of the 38 chemicals or categories recommended thus far and has not issued any final testing standards. EPA estimates show that it will take at least 18 months to issue an Advanced Notice of Proposed Rulemaking and about 5 years to issue a final test rule. Depending on the testing required, 9 or more years may elapse before a potentially harmful chemical is regulated. (See pp. 29 to 31.)

GAO did not assess the appropriateness of current test rule procedures but shares EPA's concern with the length of time required to

issue test rules. EPA is reviewing current policies and procedures with a view to streamlining the test rule development process.

NEW CHEMICALS

Because the best time to determine a chemical's potential health and environmental effects is before commercial production begins, the Toxic Substances Control Act requires that persons intending to manufacture a new chemical give EPA at least 90 days' advance notice.

The premanufacture notice review program began July 1, 1979, without final implementing regulations, formal operating procedures, or criteria on which to base decisions regarding a chemical's disposition. EPA cited the need to resolve major issues, such as the confidentiality of the reported information, as the reason. Although the regulations and operating procedures should be in place by December 1980, EPA has stopped work on developing formal decision criteria because of its proposed reorganization and staff changes. (See pp. 40 and 45.)

EPA has been operating the premanufacture review program under interim policy guidance. The experience to date gives some cause for concern because many manufacturers are not submitting toxicity or exposure data needed to effectively assess a chemical's risk. However, EPA is confident that no harmful chemical has been allowed on the market. (See pp. 36 to 39.)

According to EPA, this situation may change when the final premanufacture notice rules and forms are issued. GAO believes that EPA could use other provisions of the act related to new chemicals to increase the amount of information manufacturers are required to submit. EPA began a study in December 1979 to develop a strategy to obtain more information using various authorities of the act, but work has stopped on this task because of the proposed reorganization and staff changes. (See pp. 39 and 40.)

RECOMMENDATIONS

The Administrator, EPA, should resume work on projects to

--develop a strategy to obtain needed information on new chemicals using all of the act's authorities and

--establish evaluation criteria for each decision point in the premanufacture notice review process. (See p. 46.)

AGENCY COMMENTS

EPA commented that the report was a fair summary of its experience in implementing the act. The Agency stated that work is proceeding on developing a strategy to obtain more information in premanufacture notice forms. EPA also agreed to establish evaluation criteria for the premanufacture review process. (See p. 46.)

APPENDIX Page

III Letter dated September 8, 1980, from the Assistant Administrator for Planning and Management, EPA 49

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OTE	Office of Testing and Evaluation
OTS	Office of Toxic Substances
PCB	polychlorinated biphenyl
PMN	premanufacture notice
SOLC	Section of Law Committee
TSCA	Toxic Substances Control Act of 1976

GLOSSARY

Acute toxicity	The potential of a substance to cause adverse effects in an organism through a single exposure.
Chronic feeding/ oncogenicity study	A long-term feeding study to determine the potential of a substance to cause an increased proliferation of cells which could lead to tumor formation.
Mutagenic effects study	A study of the potential of a substance to cause any heritable change in the quantity or quality of genetic material from one generation to another.
Neurotoxicity effects study	A study of the potential of a substance to cause any physical or functional change to any nervous tissue or to cause behavior changes in an animal.
Reproductive effects study	A study to provide hazard assessment information resulting from an impairment of reproduction due to test substance exposure.
Subchronic toxicity	The total adverse effects following continuous or repeated administration of a test substance over a period of approximately 90 days.
Teratogenic effects	A study of the potential of a substance to produce effects in offspring resulting from exposure during gestation.

CHAPTER 1

INTRODUCTION

In signing the Toxic Substances Control Act (TSCA) of 1976 into law, the President stated that "this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress." For the first time, the entire chemical industry is subject to comprehensive Federal control.

THE CHEMICAL INDUSTRY--A PROFILE

The chemical industry has experienced rapid growth in the last century. Since 1967 alone, production of all chemicals and allied products has doubled; in 1978 total chemical sales exceeded $100 billion. Productivity is also increasing more rapidly than in other manufacturing industries generally.

An estimated two million recognized chemical compounds presently exist. More than 55,000 chemicals are currently manufactured in or imported into the United States, and as many as 1000 new chemicals may be introduced annually by 1982. In 1978 the production of the top 50 inorganic and organic chemicals approximated 350 billion pounds and 172 billion pounds, respectively.

Over 10,000 firms have been identified as comprising the chemical industry. However, firms with annual sales greater than $5 million account for 96 percent of the total manufacturing sales and 95 percent of employment, but represent less than 20 percent of all firms.

The chemical industry contributes significantly to the Nation's economy and represented nearly 9 percent of all U.S. exports in 1978. Although the overall deficit in the U.S. balance of trade that year was $28.5 billion, the chemical industry had a trade surplus of about $6.2 billion. Overall, U.S. chemical exports represented about 14 percent of the world total.

BENEFITS AND HAZARDS OF CHEMICALS

Chemicals play an important role in protecting, prolonging, and enhancing life. Synthetic fibers are used to replace human tissue and to create easy-to-wear wardrobes. Plastics have been molded for use in almost every phase of life--in transportation, communications, and industrial and consumer goods. Leisure time has been enhanced, for example,

by durable, low-maintenance pleasure boats and other recreational equipment made from plastics. Although countless benefits are derived from chemicals and their use, the potential hazards to health and the environment are not fully understood.

Incidents involving toxic substances emerged in the 1960s and 1970s as major public health and environmental problems. The following are examples of chemical hazards.

--The fire retardant Tris, used in sleepwear and other clothing, was found to be carcinogenic and mutagenic and could be absorbed through the skin.

--Polychlorinated biphenyls (PCBs) were found to cause liver cancer in rats and to have contaminated numerous fish stocks throughout the United States.

--Asbestos, which was used in fireproofing buildings, has become a widespread environmental contaminant for large segments of our society, and has caused fibrosis and malignancies of the lung and other organs.

The Environmental Protection Agency (EPA) Assistant Administrator for Toxic Substances in a September 13, 1978, statement before the AFL-CIO National Conference on Occupational Safety and Health commented on the risks of chronic damage to human health and the environment from toxic chemicals as follows:

> "The threats that these chemicals pose - cancer, birth defects, gene mutations, sterility, among others - are all the more insidious because of the thousands of chemicals in existence, because we know so little about so many of them, and because the gap in time between exposure and the onset of illness makes the problems of toxic chemicals less apparent than the classical problems of acute poisoning."

CLOSING THE GAPS IN ENVIRONMENTAL LEGISLATION

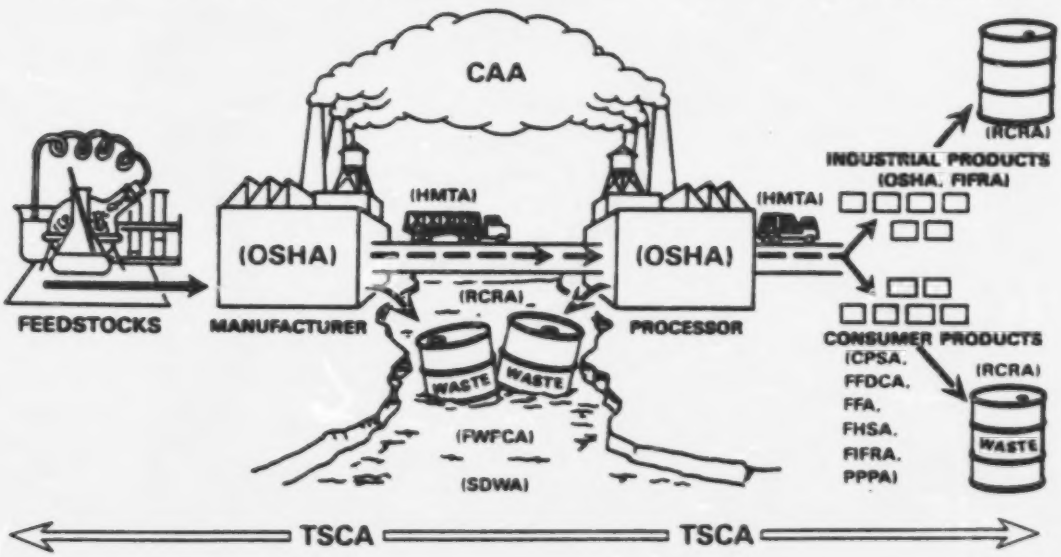
Regulating toxic substances is not new. Over the years, many laws dealing with toxic substances of one kind or another have been enacted. However, many gaps existed which allowed certain products to go unregulated or which prevented regulatory action until a product had already

caused some harm to either man or the environment. In April 1971 the Council on Environmental Quality commented on the state of then existing legislation as follows:

> "It is clear that current laws are inadequate to control the actual and potential dangers of toxic substances comprehensively or systematically. The control over manufacture and distribution pertain to only a small percentage of the chemical substances which find their way into the environment."

Recognizing the need to close the gaps in existing legislation, the Congress enacted the Toxic Substances Control Act of 1976 (Public Law 94-469). The following diagram illustrates the coverage provided by the various Federal legislative authorities affecting a chemical's life cycle.

LEGISLATIVE AUTHORITIES AFFECTING THE LIFE CYCLE OF A CHEMICAL



• KEY •

CAA	= CLEAN AIR ACT	HMTA	= HAZARDOUS MATERIALS TRANSPORTATION ACT
CPSA	= CONSUMER PRODUCT SAFETY ACT	OSHA	= OCCUPATIONAL SAFETY & HEALTH ACT
FFDCA	= FED. FOOD, DRUG, & COSMETIC ACT	PPPA	= POISON PREVENTION PACKAGING ACT
FFA	= FLAMMABLE FABRICS ACT	RCRA	= RESOURCE CONSERVATION & RECOVERY ACT
FHSA	= FED. HAZARDOUS SUBSTANCES ACT	SDWA	= SAFE DRINKING WATER ACT
FIFRA	= FED. INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT	TSCA	= TOXIC SUBSTANCES CONTROL ACT
FWPCA	= FED. WATER POLLUTION CONTROL ACT		

Source: EPA Journal, July/August 1979.

TSCA is a long and complicated piece of legislation resulting from work in three Congresses over a 5-year period. The basic objectives or policies of the act are that

> "(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
>
> "(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
>
> "(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

To carry out the objectives of the act, EPA is to:

--gather information on chemicals,

--screen new chemicals prior to manufacture,

--require testing of chemicals identified as possible risks, and

--control chemicals proven to present a risk.

Eight product categories, however, are exempt from TSCA: tobacco, nuclear material, firearms and ammunition, substances used solely as pesticides, food, food additives, drugs, and cosmetics. These products are covered by existing legislation administered by EPA and other Federal agencies.

Information gathering

Section 8 of the act authorizes EPA to issue rules requiring manufacturers and processors to maintain records and to submit such information as the Administrator reasonably requires. This information is to include the name of the

chemical, its chemical identity, its uses, estimates of production levels, description of byproducts, data on adverse health and environmental effects, and number of workers exposed to the chemical. Certain exemptions are provided for small manufacturers and processors as well as those manufacturing and processing mixtures or small quantities of a chemical substance used solely for research or analysis.

This section of TSCA also provides that

--the Administrator must publish a list of all existing chemicals and

--persons who manufacture, process, or distribute chemicals in commerce must

(1) keep records of significant adverse reactions to health or the environment that are allegedly caused by a chemical substance or mixture,

(2) submit lists or copies of health and safety studies to EPA as required by the Administrator, and

(3) report to EPA information which indicates that a chemical presents a substantial risk of injury to health or the environment, in the absence of actual knowledge that the Administrator has already been adequately informed.

Screening new chemicals

Section 5 requires manufacturers of new chemical substances to notify EPA at least 90 days before manufacturing a new chemical for commercial purposes. Any chemical which is not listed on the inventory of existing chemicals is considered "new" for purposes of the premanufacturing notice (PMN) requirement. EPA may also designate an existing chemical's use as a "significant new use" and require reporting 90 days before manufacturing or processing the chemical for that use. The PMN is to include similar information to that detailed above under section 8.

If EPA finds that information is inadequate to evaluate the health and environmental effects of a new chemical, the agency may issue an order 45 days before expiration of the 90-day review period to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical pending receipt of additional information. If the manufacturer files an objection to the order, EPA may seek a court injunction.

If EPA finds a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment, EPA may follow similar procedures involving an order and, if appropriate, court action to prohibit the manufacture of the chemical.

Testing chemicals

Under section 4, EPA may require the manufacturers or processors of potentially harmful chemicals to test the chemicals. To require testing, EPA must find that (1) the chemical may present an unreasonable risk or there may be substantial human or environmental exposure to the chemical, (2) data and experience are insufficient for determining or predicting the chemical's effects, and (3) testing is necessary to develop such data.

TSCA also established the Interagency Testing Committee (ITC), composed of representatives from eight Federal agencies, to make recommendations to the Administrator concerning testing priorities. The ITC may recommend a maximum of 50 substances or mixtures for which the Administrator should initiate a testing rulemaking procedure within 1 year. If the Administrator does not take this action within a year, EPA must publish in the Federal Register an explanation as to why such action was not taken.

Chemical control

Section 6 requires EPA to take action against chemical substances or mixtures for which a reasonable basis exists to conclude that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substances or mixtures, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment. Actions which may be taken range from a complete ban to a simple labeling requirement.

The control requirements imposed must not place an undue burden on industry; at the same time they must provide an adequate margin of protection against the unreasonable risk. Factors which must be included in EPA's decision are the effects and exposure amounts to human health and the environment; the use, benefits, and availability of substitutes; and the economic consequences of regulation on the national economy, small business, and technical innovation.

TSCA specifically requires the regulation and eventual banning of PCBs. EPA must issue labeling and disposal regulations; prohibit the manufacture, processing, distribution

in commerce, or use of PCBs in any manner other than in a totally enclosed manner after January 1978 unless EPA determines it will not present an unreasonable risk; prohibit all manufacturing after January 1979; and prohibit the processing and distribution of PCBs after July 1979.

OBJECTIVES, SCOPE, AND METHODOLOGY

Our review was designed to determine the status of EPA's efforts to implement the Toxic Substances Control Act of 1976. Special attention was given to identifying major issues confronting EPA in implementing the core program requirements of sections 4, 5, 6, and 8 related to testing, control of new and existing chemicals, and information gathering. In addition, we reviewed the organizational structure and staffing of the Office of Pesticides and Toxic Substances (OPTS).

We performed our review at EPA headquarters in Washington, D.C. We interviewed present and former OPTS officials, as well as other EPA officials in the Offices of the General Counsel and Planning and Management. We reviewed pertinent legislation, regulations, reports, documents, plans, and internal memorandums. However, much of this material was in draft form because of the evolutionary nature of the program. We also reviewed correspondence and documentation submitted to EPA by parties affected by the Toxics Program to identify issues of concern.

CHAPTER 2

PROBLEMS CHARTING A COURSE AND DEVELOPING AN ORGANIZATIONAL BASE

When the Toxic Substances Control Act was enacted in October 1976, EPA was faced with a large potential workload and only a small staff assigned to the Office of Toxic Substances (OTS). An organization had to be developed and staffed concurrent with program implementation. Progress toward meeting the act's objectives has been slow, due, in part, to the time needed to establish an organization and to chart a course of action for the program.

ORGANIZATIONAL AND STAFFING PROBLEMS HINDERED IMPLEMENTATION

Starting with less than 50 staff members in October 1976, OTS was unorganized and greatly understaffed as it began to simultaneously staff, organize, and implement the critical early stages of TSCA. The change of administrations immediately after the act was passed and the prolonged search for an assistant administrator to head the Toxics Program led to initial delays in starting up the new organization. Subsequent problems in developing and staffing the new organization also contributed to EPA's slow progress in meeting TSCA's ojectives.

Problems developing an organizational structure

Concurrent with developing an implementation approach, EPA began work on creating an organizational structure to implement the new TSCA authority. Despite a considerable amount of effort, no overall consensus could be reached among the EPA Assistant Administrators on an appropriate structure. Key issues which could not be resolved included

--to what extent the Office of Pesticide Programs and OTS should be combined and when,

--the role and organizational placement of the toxics coordination/integration function, and

--whether toxics implementation activities would be effective if placed under one deputy assistant administrator (DAA).

In a March 1977 memorandum, the Acting Assistant Administrators for Toxic Substances and for Planning and Management advised the Administrator of the need to make basic organizational decisions and the importance of initiating Civil Service Commission review of the basic deputy-assistant-administrator-level structure. The need for prompt action was explained as follows:

> "To a large degree, of course, these organizational questions hinge on the overall Agency Toxics strategy and the final allocation of Toxics resources, and have been deferred as the Agency has worked toward the resolution of strategy/resource questions. In light of implementation deadlines and normal hiring lead-times, however, it is becoming increasingly clear that further delay in developing a basic organizational framework can only serve to hamper implementation of the Act."

Several options were presented for consideration, and a recommendation was made to adopt an organizational structure consisting of three offices--Toxic Substances Control, Pesticide Programs, and a combined Office of Hazards Evaluation and Integration. After circulating a proposed organizational plan within EPA for comment, the Administrator decided to establish three Toxic Substances offices and a Pesticide Programs office, each headed by a deputy assistant administrator.

In October 1977 the new Assistant Administrator proposed an organization plan for the Toxic Substances Program consistent with the Administrator's decision to establish three toxics offices. The proposed organizational structure with eight divisions and an Office of Industry Assistance was designed to cover all of the functions necessary to implement the program. The proposal was approved by the EPA Administrator on January 26, 1978, and became effective on March 22, 1978. (See app. I.) It was not until July 1979, however, that all divisions were organized to the branch level, thus completing the organizational phase of the program.

Why it took 2-1/2 years to establish the organizational structure is not clear. EPA officials generally pointed out that the Toxics Program did not evolve from an ongoing program; therefore, key decisions had to be made before the organizational framework could be established. Others said that it just takes time to establish a new program and gain the necessary approvals within EPA. Officials in EPA's

Office of Planning and Management, however, attributed at least some of the delay to the absence of a detailed, long-term operating plan to guide program planners.

Problems hiring qualified staff

Until recently, the recruitment of scientific and managerial staff has fallen far short of authorized levels. This problem was cited by EPA officials as the major reason for the delays encountered in implementing the act.

EPA officials said that the recruitment of senior management staff was initially delayed pending the approval of an organizational structure on which to base position discriptions. As shown below, key management positions were vacant during the critical early phases--the first 3 years--of TSCA implementation.

Position (filled)	Officially assigned
Assistant administrator (1)	October 1977
Deputy assistant administrators (3)	January-July 1978
Division directors (8)	June-October 1978
Branch chiefs (16 of 25)	January-October 1979

With key management positions vacant, particularly branch chiefs, staff recruiting was slowed. Division Directors interviewed said that their time had to be divided between program implementation and hiring activities.

The program's hiring problem has been heightened by a shortage of scientists in the job market. The Assistant Administrator for Toxic Substances testified in September 1977 that

> "* * * the enactment of TSCA, together with increasing public concern over the health effects of chemicals generally, has put enormous strains on the nation's small cadre of environmental health scientists. There simply are not enough trained experts in toxicology, pharmacology, epidemiology, and related professions to meet the new and growing requirements of government and industry."

Information we provided at the request of the Chairman, Subcommittee on Consumer Protection and Finance, House Interstate and Foreign Commerce Committee, supports this statement. In December 1978 we informed the chairman that the demand for scientists outpaces the current supply, particularly for toxicologists, pathologists (veterinary), epidemiologists, and industrial hygienists. We said that the effect of the shortages could be a delay in implementing TSCA, a decline in the quality of chemical research, and a lack of qualified Government personnel to make regulatory decisions.

According to EPA officials, the limited supply of scientists, critical office space shortages, and the average 3-4 month delay from the time an authorized position becomes available until the person actually reports for work continue to impede staffing. The following table shows how recruitment for the Toxics Program has lagged behind authorized levels.

OPTS Permanent Positions

	Fiscal year			
Staffing level	1977	1978	1979	1980
Authorized	88	196	382	510
Actual	88	171	313	a/423
Shortfall	-	(25)	(69)	(87)

a/As of May 2, 1980.

Even if EPA reaches the authorized staff ceiling, it is questionable whether EPA will have adequate resources to effectively carry out all TSCA responsibilities. In its fiscal year 1979 budget submission to the Office of Management and Budget, EPA stated:

> "* * * The resources available or absorbable in the next few years do not begin to be adequate to meet total expected program needs; a conservative estimate of the number of people needed for the implementation stage appropriate to FY 1979 is on the order of 1,500, with no allowance for startup inefficiencies."

In a June 20, 1980, internal memorandum discussing the fiscal year 1982 budget, the Assistant Administrator, OPTS, commented that the resources currently devoted to test rule-development and risk-assessment processes limited EPA to

developing test rules only for ITC-recommended chemicals and supporting only two or three control actions on existing chemicals annually.

PROGRAM DIRECTION HAS BEEN UNCLEAR

Although EPA had a small staff assigned to OTS as early as 1971, little advance planning had been done to implement TSCA. No final strategy to guide program implementation had been developed in anticipation of the act's passage and no plan existed for developing one.

No clear strategic plan was developed to guide program implementation

Long-range strategic planning would describe a comprehensive approach to improving long-term regulatory effectiveness by identifying opportunities with specific expected policy results in mind. It would enable EPA to anticipate strategic problems or to grasp opportunities before they occur, thereby allowing sufficient leadtime for an appropriate course of action to be developed. Policy planning, on the other hand, would provide the means, through the constant reexamination of the environment in which EPA operates, to reduce, if not eliminate, a "crisis-to-crisis" style of control by broadening management's time-span perspective and providing an opportunity to deal with substantive program matters.

On October 22, 1976, the Deputy Administrator established the TSCA Strategy Work Group to develop an implementation strategy. Public meetings were held in December 1976 followed by the publication of a February 1977 draft strategy outlining possible implementation approaches. The draft, designed to stimulate public comment, addressed the major TSCA requirements and was described as a first step in developing a comprehensive program strategy.

A considerable amount of time and resources was devoted to continuing the strategy effort into 1978, but no agreement could be reached on any one approach. A special assistant to the Assistant Administrator during this period told us that a consensus could not be reached among the committee members on any one strategy. When it was apparent that a strategy was not forthcoming, the Assistant Administrator, OPTS, and his staff produced a draft strategy, dated January 23, 1978. This was presented to the Strategy Work

Group of the Administrator's Toxic Substances Advisory Committee which commented, in part, as follows:

> "The Agency's course in implementing TSCA is difficult to follow; needs to be more explicit, in terms of needs and methods; needs a sense of sequence progression and parallel activities * * *."
>
> * * * * *
>
> "A time course is not clear regarding long term goals and midterm objectives."

Based on a review of the comments received from the committee and others, EPA published a revised strategy in the Federal Register on October 26, 1978, entitled "Proposed Implementation Approach: Request For Public Comment." This document represented the then most current approach (although admittedly not a comprehensive approach) to implementing the act. The stated objectives were to:

--Develop the necessary organization and staff.

--Define methods for assigning priorities to chemical substances for investigation and regulation.

--Establish procedures for testing and evaluating chemical hazards.

--Initiate information gathering.

--Establish mechanisms for premanufacture notification of new chemical substances.

--Take selective regulatory actions.

--Develop a coherent agencywide approach to toxic substances.

--Work toward consistent international approaches to toxic substances control.

The proposed approach outlined, in general terms, how each major functional activity would be addressed. Specific time frames for completing the stated objectives were not provided. Instead, the objectives were to be addressed during the early years of implementation. Also, clear-cut priorities were not assigned to the various activities except to the extent that the development and implementation of the premanufacture review program was identified as the top priority activity.

Only 22 comments were submitted in response to the Request for Public Comment. Most of the responders directed their comments to specific concerns rather than to EPA's overall implementation approach. However, seven responders did comment on the overall approach. Specific comments were:

> "The document outlines a reasoned approach to implementing TSCA. Our primary recommendation is that the forthcoming regulations and guidelines will, in fact, reflect this reasonable and common sense strategy * * *."
>
> * * * * *
>
> "* * * EPA has properly identified its basic objectives. In addition, EPA is to be commended for drafting objectives which establish a reasonable working framework for implementing TSCA. Unfortunately, the approach was described in such vague terms that it is difficult to offer specific comments."
>
> * * * * *
>
> "The objectives, although discussed later in the proposal, are so general, perhaps necessarily so, as to make comment in any depth difficult."
>
> * * * * *
>
> "The implementation approach described by EPA exhibits no sense of urgency. While priorities are discussed, there is no time framework even for the highest priority areas, except for reference to 'the early years of implementation.'"

Since the October 1978 proposal, EPA has devoted little effort to completing a strategy guidance document. The Assistant Administrator attributed this to the need to begin implementing the programs mandated under TSCA.

Although a formal written strategy never evolved, the Assistant Administrator, OPTS, has provided other guidance to the staff in various ways. These include (1) the zero-base budget process, (2) Office of Management and Budget submissions, and (3) the operating year plans. In addition, a February 16, 1979, memorandum to the staff outlined his objectives for achieving TSCA's goals. This memorandum listed general as well as specific program objectives for fiscal years 1979 to 1981. The general objectives were intended to give a sense of what the thrust and tone of the

program should be, whereas the specific objectives were given in terms of expected outputs to achieve the general objectives. Examples for fiscal year 1979 include proposing the first section 4 test rule and proposing a section 6 regulation banning or limiting the use of one existing chemical.

However, as late as September 1979, the direction of the program still appeared to be in doubt. This is apparent from the comments provided to the Assistant Administrator on September 28, 1979, in response to his September 19, 1979, memorandum concerning TSCA strategy/policy issues. Two Deputy Assistant Administrators commented as follows:

> "There is as yet no coherent OTS-wide view of TSCA's essential purpose, and hence no agreement except by coincidence as to how we should implement it. Rather, there is a Section 5 program, a Section 4 program, a Section 6 program, a Section 8 program, etc,, each apparently driven to a greater or lessor degree, by the inevitable bureaucratic imperatives of (1) self-preservation, and (2) exercise of an authority because it is there * * * In short, means are taking precedence over ends."

* * * * *

> "It addresses a key issue [the primary objective to be sought under the Act] that has gone unresolved ever since I have been associated with OTS * * * It is extremely important, whatever the basic approach taken by OTS in implementing TSCA, that it is clearly understood by all OTS staff. To leave the basic thrust of TSCA implementation vague or unresolved creates confusion, inefficiency, and unnecessary internal frictions. Without a clear approach, individuals and various segments of OTS cannot get a clear view of their priorities, goals or role in the big picture."

These comments were not unlike those expressed by other program officials during our review. They stated that clear-cut priorities had not been established or were constantly changing and that the divisions were not sure of their functional relationship in the organization.

In December 1979 strategic and policy issues related to TSCA implementation were discussed at a senior management

"retreat" in Harpers Ferry, West Virginia. This retreat brought to a head many of the concerns expressed above. Major accomplishments of the retreat included

--agreement on the conceptual framework that would guide EPA in the continued implementation of TSCA,

--agreement on a selected number of key objectives that OPTS should attempt to achieve over the next 5 years, and

--agreement on the relative emphases that would be placed on different areas of TSCA activities.

But, as indicated in the March 14, 1980, summary report of the meeting, this effort is only a beginning.

> "* * * A number of specific tasks coming out of the retreat have to be completed. * * * Additional time will have to be spent to resolve issues not resolved at the retreat. The OPTS management plans, operating plans, and budget will have to be developed and implemented in accord with decisions made at the retreat. And there will have to be additional retreat type meetings to resolve other operational or strategic questions facing OPTS in implementing TSCA."

Efforts to develop a planning system

OPTS has not had a formal, operational planning function during much of its organizational life. The need to establish a systematic planning approach was recognized by the Office of Policy Analysis and Management (OPAM) in January 1979. An OPAM official told us that very little systematic, formal planning had been performed before 1979 and that the program was operating in a crisis mode.

Recognizing the need for a formal planning approach, the Assistant Administrator for Toxic Substances included the development of a detailed program planning system for each of the three toxics offices in his February 16, 1979, guidance memorandum. In April 1979 OPAM contracted with the Management Analysis Center, Inc. (MAC), to assist them in developing the planning approach.

Between May and July 1979, OPAM/MAC developed a planning approach, a proposed framework, and an implementation schedule. Since planning would be decentralized, all DAA's were requested to document their planning systems according to criteria established by OPAM/MAC and to begin testing the system in fiscal

year 1980. In addition, a work-planning concept, known as Section of Law Committee (SOLC) planning, was adopted to overcome some of the past problems encountered in planning projects requiring support from other divisions within OPTS.

The DAAs submitted their planning systems to OPAM between August and November 1979, and implementation of the planning systems began thereafter. Concurrent with this work, SOLC committees were established for each of the four major sections of TSCA: sections 4, 5, 6, and 8. The committees--composed of division directors--were responsible for reviewing individual project plans and making milestone and resource commitments to carry them out.

Initially, the Assistant Administrator selected 12 projects for the SOLC process. Plans for five of the projects were completed in October 1979, and resources were committed to two of these in February 1980. Program officials told us that implementation of SOLC planning has been hindered by the lack of resources, particularly in the Office of Testing and Evaluation (OTE), to carry out the plans.

Due to the reorganization proposed in March 1980, implementation of the DAA planning processes was halted. However, a project planning system has been developed for the proposed new Office of Toxic Substances. Under this system, the DAA and the new Committee of Division Directors will develop planning guidance establishing the overall program direction as well as the individual project priorities needed to achieve the objectives. This guidance will be used to initiate the development of detailed workplans.

MAJOR REORGANIZATION: AN ATTEMPT TO CORRECT PROBLEMS

On March 7, 1980, the Assistant Administrator proposed a reorganization for the Toxics Program. (See app. II.) The primarly reasons cited for the reorganization were:

> "(1) to increase the emphasis being given to toxics integration within EPA and across other federal agencies, and (2) to eliminate many of the organizational and administrative problems we have experienced with the current matrix organization which has the TSCA responsibilities divided among three Deputy Assistant Administrators."

The major change would be a consolidation of the TSCA implementation responsibilities of three DAAs into one office of the DAA for Toxic Substances. In addition, two new associate assistant administrator positions would be established: one

responsible for developing toxics-related program integration and chemical information systems and the other for developing regulatory strategies. One benefit cited was that the new structure would provide a much clearer recognition of the authority and functional relationships within the program.

Other operational changes would include

--the consolidation of the entire chemical exposure assessment process into one division,

--the consolidation of all regulatory functions into one division, and

--the consolidation of all information rulemaking authority into the division which is the major user of the information.

CONCLUSIONS

EPA has had difficulty developing and staffing the new Office of Pesticides and Toxic Substances and charting a course of action to guide program implementation. Together, these factors have contributed to initial delays in implementing the Toxics Program. In addition, there is some indication that the resources currently allocated to the program may be inadequate. However, until EPA has had an opportunity to finalize its operating procedures and gain experience using them, as described in the following chapters, we believe it is too early to determine whether additional resources are needed.

EPA management has taken action on two fronts to address both operational and management problems which have reduced the short-term effectiveness of the program. First, a senior management retreat was held in December 1979 during which agreement was reached on a conceptual framework to guide program implementation as well as other policy and strategy issues. Second, EPA announced a major reorganization in March 1980 which would consolidate many of the prior OPTS activities and give one DAA full responsibility for carrying out the TSCA program.

Although a temporary slowdown of ongoing activities can be expected, these actions should have a positive effect on the future course of the Toxics Program. Further, we believe that the recent establishment of a formal planning process, if implemented as indicated, should provide needed direction to the program.

CHAPTER 3

CONTROLLING EXISTING CHEMICALS: A RELATIVELY LOW EPA PRIORITY

Every day people are being exposed to thousands of chemical substances whose potential harmful effects are little known. Although TSCA gave EPA broad new authority in 1976 to correct this situation, the public is not much better protected today.

EPA has been slow to collect basic information on chemicals. During the first years of program implementation, it has placed less emphasis on assessing the potential risks of existing chemicals and controlling those found to present an unreasonable risk than on other TSCA mandates. Also, EPA has not required chemical manufacturers or processors to test potentially harmful chemicals despite the fact that it must respond to ITC recommendations for priority testing within 1 year.

EPA's limited progress in addressing the problems of existing chemicals seems to be directly related to the level of resources EPA has assigned to this activity. According to EPA, current resources devoted to assessing chemicals precludes

--initiating test rules on other than ITC priority chemicals, and

--supporting more than two or three control actions a year.

EPA HAS BEEN SLOW TO COLLECT BASIC INFORMATION

When TSCA was passed, little or no information existed on the number of chemicals in commerce, how they were being used, who was being exposed, and which ones were toxic. Despite almost 4 years of activity, EPA has not collected this information on existing chemicals. Specifically, EPA

--has obtained only production-related information while compiling the chemical inventory,

--has not requested chemical use and exposure information or health and environmental effects data,

--has requested and obtained health and safety studies on only 10 chemical substances, and

--has been slow to implement other recordkeeping and reporting requirements.

The chemical inventory limited to chemical identity and production data

TSCA required EPA to promulgate inventory reporting rules and publish an inventory of all existing chemicals by June 29, 1977, and November 1977, respectively. EPA missed both of these deadlines because major questions concerning the scope of the inventory-reporting rule could not be resolved. Questions included: Should the inventory be simply a list of chemicals or be viewed more broadly to include the development of a comprehensive data base? Who should report this information?

EPA initially proposed a reporting rule on March 9, 1977, which would have required manufacturers, importers, and processors to report only the identity of chemicals in commerce. However, after reviewing the comments received, EPA decided to repropose the rule and expand its scope to include the submission of information necessary to develop a profile of the chemical industry.

EPA issued a two-phase final reporting rule in December 1977. It selected this reporting strategy to reduce the burden on those submitting the information by eliminating duplicate reporting. During the first phase, manufacturers and importers reported the identity of all chemicals manufactured or imported in bulk since January 1975. With certain exceptions for small firms, they also reported where the chemical is produced, in what quantities, and whether it is distributed beyond the production site. An initial inventory of over 43,000 chemicals was published on June 1, 1979.

In the second phase, a 210-day period beginning with the publication of the initial inventory, chemical processors and importers of chemical substances as part of mixtures or articles reported other chemicals not reported by the manufacturers. A revised inventory was published on July 28, 1980, bringing the total number of chemicals subject to TSCA to 55,103.

EPA did not request use, exposure, or other information because it would place a burden on manufacturers and delay publication of the inventory. Instead, EPA's strategy was to request more information in follow up rules beginning as early as the fall of 1977. In the first such rule, EPA planned to include a "substantial number of chemical substances selected because of their priority to the Occupational Safety and Health Administration and other agencies, as well as EPA".

Use, exposure, and effects data not obtained

Although use, exposure, and health effects data is important in determining the priority of chemical substances for action, implementing the significant new use requirements for existing chemicals, and in initiating testing requirements, EPA has not obtained this information. In fact, it was not until February 1980 that EPA proposed a rule requesting exposure-related information.

Several reasons were given by the Director, Program Integration Division, and other officials for the delay in requesting additional information. They said that basic questions had to be resolved, including who would be the ultimate user of the information, what information should be requested, and for what chemicals. However, these could not be answered until EPA decided on an approach to assessing chemical risk.

Once a framework for the assessment process was established in 1978, EPA developed a strategy to request information as it would be needed in the chemical review process. Using TSCA section 8(a) authority, a series of rules--referred to as Level A, B, and C rules--would be developed to provide increasingly more detailed information as needed in assessing a chemical's risk.

Level A--designed to provide exposure-related information, including general use information, useful in selecting chemicals for review.

Level B--designed to provide information in the first in-depth assessment phase. More detailed use, exposure, and toxicity information will be gathered.

Level C--designed for the detailed questions that must be addressed in identifying what regulatory controls are needed for individual chemicals.

In this way EPA would be able to target its resources on the worst chemicals while minimizing industry's reporting burden.

In January 1979 EPA began work on the first Level A rule. Since this was not a high priority activity and the principal user of this information--the Office of Testing and Evaluation--was understaffed, EPA officials said that they had difficulty getting OTE support in developing the

rule. In addition, delays were encountered because the inventory was not on the computer and programs had to be developed to obtain information from the inventory. Nevertheless, EPA proposed the Level A rule on February 29, 1980, to gather exposure data on about 2,300 substances. The chemicals were selected from many sources, including the chemical inventory and the ITC master list of chemicals of interest to other Federal agencies. This rule is scheduled to be finalized by the end of 1980. Level B and C rules are scheduled to be proposed in February and November 1981, respectively, with final rules issued about 6 months later.

Few health and safety studies have been requested 1/

Under TSCA, EPA must issue rules to require persons manufacturing, processing, or distributing chemicals to submit lists and/or copies of health and safety studies performed on chemical substances. On July 18, 1978, EPA issued its first rule to request copies of unpublished health and safety studies on the first 10 substances ITC recommended for priority testing.

On September 15, 1978, Dow Chemical Company filed a petition for review of the rule in the United States Court of Appeals for the Third Circuit. The petition challenged the scope of EPA's statutory authority

--to obtain studies on chemicals manufactured or processed for research and development purposes and

--to obtain studies on a chemical from companies that do not manufacture, process, or distribute that chemical.

Although the rule was challenged, companies, including Dow, submitted 368 studies which had been performed on the 10 chemicals or chemical categories.

On January 31, 1979, EPA revoked the rule even though the court proceeding was incomplete. The reasons cited for this action were that (1) it appeared that almost all of the

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1/Health and safety study means any study of an effect of a chemical substance or mixture on health or the environment or on both (for example, long- or short-term tests of carcinogenicity and industrial hygiene surveys).

important information requested had been received, (2) substantial questions were raised concerning whether adequate notice and comment were provided on some of the provisions contained in the July 18, 1978, rule, and (3) EPA could best use its resources by revoking the rule and considering all the issues in the next proposed rule. Despite the fact that EPA revoked the rule, the Court of Appeals on August 24, 1979, sustained EPA's interpretation of its authority to obtain the requested health and safety data.

EPA proposed a second rule requiring the submission of health and safety studies on December 31, 1979. As proposed, health and safety studies would be submitted for all ITC-recommended chemicals as well as other chemicals separately selected by EPA. In addition, future ITC recommended chemicals would automatically become subject to the reporting requirements of this model rule.

Recordkeeping and reporting requirements not fully implemented

TSCA section 8 requires chemical manufacturers, processors, and distributers to

--notify EPA, starting on January 1, 1977, when they receive information which reasonably supports the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment and

--maintain records of significant adverse reactions (as defined by the Administrator by rule) alleged to have been caused by a chemical substance or mixture.

EPA published guidance containing its interpretation of and enforcement policy on the substantial risk reporting requirement on March 16, 1978.

EPA has not issued a final rule to implement the significant adverse reaction reporting requirement. EPA has been working for 2 years to develop a rule to require companies to maintain records of allegations made by employees, customers, or others that a chemical caused a significant adverse reaction and to report these allegations to EPA upon request. EPA proposed a rule in July 1980 which would require chemical manufacturers, processors, and distributors to keep records of employees' adverse health reactions for a period of 30 years and of others for 5 years. The project

manager responsible for this rule expects the rule's record-keeping section to be in place by early 1981. However, EPA must still determine when this information should be reported.

Several factors contributed to delays in issuing the significant adverse reaction rule. EPA officials said that a draft rule was completed in December 1978, but a management decision was made to expand the definition of significant adverse reaction to more accurately reflect congressional intent. The revised rule was completed in May 1979 and was distributed for comment within EPA. After 14 months of review, the proposed rule had not changed significantly from the May 1979 draft, according to officials responsible for the rule. The Branch Chief attributed the lengthy review time to the organizational structure, to a general lack of rule-making experience within the toxics office, and to an attempt to nail everything down to the nth degree.

EPA HAS BEEN SLOW TO ASSESS THE RISKS OF EXISTING CHEMICALS

Chemical assessment is a key function supporting most other TSCA activities, including testing, screening new chemicals, and controlling existing chemicals. However, a system for selecting candidates for review, procedures for performing the assessments, and criteria for determining what action to take are still being developed.

Although more than 55,000 existing chemicals are subject to TSCA, EPA believes that probably only a small percentage are harmful. The number of chemicals which should be controlled, however, will not be known until EPA systematically assesses their potential risk. In a June 20, 1980, memorandum, the Assistant Administrator, OPTS, informed the Administrator that

> "* * * At present, a relatively low level of assessment activities leads to only 2 - 3 actions on chemicals initiated per year. If we want to take a more aggressive posture with respect to existing chemicals, we will have to devote more resources to the assessment process."

Procedures for performing assessments are not complete

When TSCA was enacted, no formal procedures existed for reviewing chemical risk. Reviewers had only a general idea of what information was needed for decisionmaking purposes, how it was to be obtained, or how it should be presented. In the spring of 1978, a basic framework was developed for

performing risk assessments. However, it was not until January 31, 1980, that EPA issued interim management plans describing the procedures for performing the comprehensive and priority problem assessments.

The comprehensive assessment process consists of an initial screening phase followed by the preparation of a Chemical Hazard Information Profile and three detailed assessment stages. At each step in the process a decision must be made on whether the chemical should proceed to the next higher step. Other options include dropping the chemical from further consideration, referring it to another agency, requesting that testing be performed, or referring it to the priority problem assessment process. These decisions are now being made on a case-by-case basis.

As the number of chemicals in the process increases, criteria will be needed to assure that decisions are consistent and defensible. A formal system of setting priorities will also be needed so that resources are applied to chemicals of greatest concern. Decision criteria will be developed in fiscal year 1980, according to EPA officials, and the Oak Ridge National Laboratory is developing a chemical scoring and ranking system for EPA. This system should be completed by October 1980, at which time a contractor will be selected to perform the actual scoring.

The priority problem assessment process is similar to the comprehensive assessment process but is designed to address potentially high-risk chemicals in a more timely manner. However, EPA has not established criteria to determine which chemicals should be afforded priority treatment. This is a major concern because of the TSCA mandate that prompt action be taken on chemicals which may cause cancer, gene mutations, or birth defects.

Beginning January 1, 1979, EPA was to take action within 180 days, or 270 days if extended for good cause, on any chemical substance or mixture for which information was received that

> "* * * indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects. * * *"

The Administrator must initiate appropriate action to prevent or reduce to a significant extent such risk or publish in the Federal Register a finding that such risk is not unreasonable.

On February 26, 1979, the Assistant Administrator for Toxic Substances outlined for the Administrator the four major issues involved in implementing this TSCA requirement and identified the steps that would be taken to resolve them. The memorandum stated, in part:

> "We will establish a high threshold for determining that information is subject to section 4(f). Most chemical carcinogens, mutagens, and teratogens which the Agency may regulate under TSCA would not be subject to section 4(f). We will attempt to develop specific operational criteria beyond the general language of the Act."
>
> * * * * *
>
> "* * * Because information submitted anywhere in the Agency could be subject to section 4(f), OTS intends to alert the other program offices in the Agency of our obligation under this section. * * *"

However, EPA has not developed operational criteria to implement this legislative requirement and has not informed other EPA program offices of their responsibilities. Key issues which EPA has not resolved include

- --how high a threshold to set for making the chemical a section 4(f) problem;
- --what action to take on information which was in the Administrator's possession before January 1, 1979;
- --how to handle chemicals which are determined to be inappropriate for regulation under TSCA; and
- --what action to take after the 180-day period expires.

An issue paper prepared for the December 1979 senior management retreat pointed out EPA's failure to develop this criteria, but because of time constraints, the issue was not discussed. However, EPA is now in the process of developing operational criteria and a policy statement on how it will implement this TSCA requirement. On May 5, 1980, OPTS resolved several of the above issues and circulated draft criteria for comment. As of July 1980, a draft policy

statement was being reviewed and EPA's Office of the General Counsel was resolving legal questions associated with implementing this requirement.

On June 3, 1980, a former EPA employee, noting that EPA received information in December 1979 that benzene was a known carcinogen, petitioned EPA under TSCA section 21 to perform those actions specified by section 4(f).

Status of assessments

Of the more than 55,000 existing chemicals, a total of 947 chemicals had been screened as of February 22, 1980. Of these, 514 were dropped from further consideration either because (1) they were not on the TSCA inventory, (2) the study showed low toxicity or negative results, or (3) the chemical was already being evaluated by another agency or EPA office. The assessments are continuing for the remaining 433. In addition, Chemical Hazard Information Profiles have been completed on 80 chemicals and are in preparation for an additional 17, as of June 20, 1980.

The following table shows the status of all chemicals which had progressed beyond the initial screening phases as of April 28, 1980.

Chemical Evaluations Performed

Assessment stage	Number of assessments Completed	In preparation	Awaiting resources
Phase I (Initial assessment)	a/4	10	10
Phase I (Validation)	0	1	b/1
Phase II (Detailed assessment)	0	2	0
Special assessments	0	2	0
Priority review	1	8	2

a/Assessments were completed in 1978 and no further action will be taken under TSCA.

b/Completed phase I in January 1979.

Although the table shows where the various chemicals are in the assessment process, an OTE official told us that not all of these are being actively worked on. This official said that during 1979, efforts to review existing chemicals almost came to a halt because the staff was temporarily reassigned to help develop test rules for the ITC chemicals. The Director of the Assessment Division said that only 10 chemicals or chemical categories were being actively reviewed as of June 1980.

Reviewing the thousands of existing chemicals to determine their potential risk will take years. For example, on March 22, 1977, the Administrator made a commitment to seriously examine 15 chemical substances for possible regulatory action. For each of the chemicals selected there was significant evidence of injury to either human health or the environment. More than 3 years after this commitment was made, a disposition has been made on only 3 of the 13 chemicals which were entered into the assessment process (lead and polybrominated biphenyls did not enter the assessment process). Tris, phosphates, and hexachlorobenzene were dropped from further consideration after completing the phase I assessment. Of the remainder, seven are currently being assessed while three others are still awaiting resources.

This example may overstate the time needed to assess chemicals because of problems such as inadequate staffing and a lack of procedures. However, the recent interim management plan for performing a comprehensive risk assessment states that it may still take as long as 2 years to complete an assessment of one chemical even if sufficient staff and information are available.

INDUSTRY NOT REQUIRED TO TEST CHEMICALS

EPA may require chemical manufacturers and processors to test chemicals which may pose an unreasonable risk, but which have not been adequately tested. To assist EPA in selecting chemicals for testing, TSCA established the Interagency Testing Committee, which may recommend up to 50 substances for priority testing. EPA then has 1 year to either start rulemaking procedures to require the recommended testing or to specify its reasons for not doing so.

EPA's progress to date has been disappointing. No test standards describing how specific tests should be performed or test rules requiring manufacturers or processors to test a chemical have been issued. In addition, EPA has not adequately responded to ITC recommendations.

Only health effects test standards have been proposed

Before EPA can require chemical manufacturers or processors to test their chemicals, it must issue test standards defining how the test should be performed. EPA proposed its first health effects test standards for chronic effects, as well as standards describing good laboratory practices, on May 9, 1979. These were followed on July 26, 1979, by proposed standards for acute and subchronic toxicity, mutagenic effects, teratogenic effects, reproductive effects, and metabolism studies. Another set of health effects test standards to include neurotoxicity testing are being developed. According to EPA, proposed and final health test standards will be issued in the spring of 1981.

In addition to health effects test standards, EPA will develop as many as 62 environmental effects test standards in a series of 11 groups. But progress in developing these standards has not kept pace with the health standards. The first environmental test standards will be proposed in September 1980. Subsequent environmental test standards will be proposed over a 2-year period beginning in March 1981.

EPA officials attribute this slow progress to staffing problems. They said that hiring qualified scientists is difficult and that only recently have actual staffing levels approached those authorized. In addition, they said that the state of the art with respect to environmental effects testing is such that only a small amount of information is available from any source on which to base the standard.

Test rules have not been developed

Once the test standards are in place, EPA can specify which chemicals or groups of chemicals should be tested and for which health and environmental effects. Although EPA may determine, as a result of problems identified in its reviews, that certain existing and new chemicals should be tested, currently all test rule resources are allocated to ITC chemicals.

ITC met for the first time on February 7, 1977--2 months ahead of the statutory deadline--and issued its first report in October 1977 recommending priority testing for 10 chemicals or chemical categories. In subsequent reports, issued at 6-month intervals, an additional 28 chemicals have been recommended to EPA. On all but five of these chemicals, the 1-year deadline passed without EPA initiating action to require the recommended testing. EPA, however, responded to the first ITC report by stating that it was still in the process of

evaluating the recommended chemicals and that proposed test rules could not be issued until relevant test standards had been proposed.

On May 8, 1979, the Natural Resources Defense Council filed suit against EPA for its failure to take action on the ITC recommendation. According to EPA, the United States District Court for the Southern District of New York ordered EPA to submit a compliance plan.

The Assistant Administrator, OPTS, informed the court that rather than issue a proposed rule to initiate the rulemaking procedure, EPA will now publish an Advanced Notice of Proposed Rulemaking (ANPRM) in the Federal Register. Since an ANPRM requires less development and review time than a proposed rule, he said that EPA will be more responsive to the 1-year legislative requirement for initiating a rulmaking procedure. However, a June 2, 1980, compliance schedule (current draft) shows that at least 18 months will be required to issue an ANPRM and that, generally, more than 5 years will be needed to issue a final rule.

	Average number of months estimated to issue a final test rule	
Date ITC recommended chemicals for testing	Health effects	Environmental effects
October 1977	70	76
April 1978	67	71
October 1978	68	78
April 1979	66	85
October 1979	59	59
April 1980 (note a)	77	77

a/EPA estimate, not an average.

In addition to the 5 years to issue a test rule, several years may be required to perform the test, analyze the results, and control a chemical which is found to present an unreason-

example, a chronic feeding/oncogenicity study is required, 9 or more years may elapse before action can be taken to protect the public.

On July 18, 1980, EPA proposed test rules for the chemical chloromethane and for the chemical category, chlorinated benzines. At the same time EPA proposed an exemption from testing requirements for acrylamide. EPA officials attribute the considerable delay in getting out the first test rules to the time needed to resolve basic questions related to how much support is needed to justify testing and what must be done to show that existing tests are inadequate.

One reason it takes so long to issue a test rule is EPA's policy of reviewing about 95 percent of all published material on a chemical, going back as far as 30 to 50 years. For benzedine dyes, the Director, Chemical Information Division, told us that this represented about 400 literature searches resulting in about 35,000 references. In his opinion, most relevant information on chemical research can be found within the last 10 to 15 years at roughly half the cost. Other EPA officials, however, are concerned that if they do not evaluate the majority of the studies already performed, industry could challenge the rule by citing studies favorable to its position which EPA has not evaluated. This would necessitate a reproposal of the test rule and therefore might delay issuance of a final rule.

Another factor mentioned as a reason for the time taken to issue a test rule is EPA's policy of exploring all of a chemical's possible health and environmental effects, not just those recommended by ITC. From a technical standpoint, EPA officials believe that looking at other effects can give a better understanding of the specific effect to be tested as well as indicate any synergistic effects. From an administrative standpoint, looking at all effects at one time rather than individually is more cost effective. However, review of the numerous health effects entails a more complex and time-consuming information gathering and rule development process.

EPA officials are concerned with the length of time required to issue a test rule and are actively reviewing the current policies and procedures with a view to streamlining the process. Some tentative decisions were made at June 3, 1980, management retreat and staff work is continuing on revising the current procedures.

FEW CONTROL ACTIONS HAVE BEEN TAKEN

Shortly after TSCA was enacted, EPA officials expressed confidence that quick action would be taken on hazardous

chemicals already in commerce. However, EPA has only regulated PCBs as required by TSCA, banned the use of chloroflourocarbon (CFC) propellants in aerosol containers, and proposed a rule to ban the movement of dioxin wastes. In 1980 EPA plans to initiate rulemaking for asbestos.

TSCA specifically provided for the control of PCBs. In addition to prescribing the disposal methods and labeling requirements for PCBs by July 1, 1977, the act prohibited, with certain exceptions, the manufacture, distribution, and use of PCBs in other than a totally enclosed manner. EPA missed all but one of the legislative deadlines for issuing the PCB rules, as follows:

--Disposal and labeling rules were issued on February 17, 1978, or more than 7 months late.

--The manufacture, distribution in commerce, and use of PCBs except in a totally enclosed manner was banned on July 1, 1979, or 18 months late.

--The manufacture of any PCB was banned on July 1, 1979, or 6 months late.

--The processing and distribution of PCBs was banned on July 1, 1979, as required by TSCA.

EPA has taken two other regulatory actions.

--On March 17, 1978, all nonessential uses of CFC propellants in aerosol containers were banned under the combined authorities of TSCA; the Federal Food, Drug, and Cosmetic Act; and the Consumer Product Safety Act. This was the first control action taken which was not directly called for under TSCA.

--In April 1980 EPA issued an "immediately effective" rule prohibiting Vertac Chemical Corporation from disposing of dioxin-contaminated waste and requiring others intending to transfer dioxin-contaminated wastes for disposal to give EPA at least 60 days' advance notice. This action was based on the Administrator's determination that the movement of dioxin wastes presented an unreasonable risk of serious injury to health or the environment.

In addition to action already taken, EPA is working on two rulemaking initiatives to reduce the exposure to asbestos--a chemical which has been shown to contribute to increased risk of lung damage and cancer. ANPRMs covering asbestos in

school buildings and the commercial and industrial use of asbestos were issued on September 20 and October 17, 1979, respectively.

Three separate asbestos rules are scheduled to be proposed in fiscal year 1981:

--A proposed rule requiring all public schools to inspect, sample, and analyze for any friable asbestos material (material that crumbles under hand pressure).

--A proposed rule requiring school districts to take corrective measures for any asbestos hazards found.

--A proposed rule to eliminate all nonessential uses of asbestos.

CONCLUSIONS

EPA has placed a relatively low emphasis on identifying and controlling existing chemicals during the first years of TSCA implementation except where required by law. However, EPA is making progress. Several initiatives are now underway which, when completed, should improve EPA's ability to systematically address potentially harmful existing chemicals.

Once all of the various parts of the regulatory program for existing chemicals are in place, the question then becomes one of resources. According to EPA, current funding of the assessment activities will result in two or three control actions annually. In addition, if the assessment determines that insufficient data exists on the chemical, EPA does not have the resources to support the development of a test rule.

In addition to systematically identifying and controlling potentially harmful chemicals, TSCA also requires EPA to initiate action

--within 180 days of receipt of information which indicates that a chemical may cause cancer, gene mutations, or birth defects and

--within 1 year on chemicals recommended by ITC for priority testing.

Although the requirement to take action on high-risk chemicals went into effect on January 1, 1979, EPA has still not developed criteria to implement this TSCA requirement or

notified other EPA offices of their responsibilities for compliance. EPA is now in the process of resolving several issues related to this requirement, including

--what action should be taken on information available to the Administrator before the effective date of the TSCA requirement,

--how high a threshold should be set for making the chemical a section 4(f) chemical,

--how EPA should handle chemicals which are not appropriate for control under TSCA, and

--what appropriate action could be taken following the 180-day period.

These issues must be resolved before EPA can effectively meet the clear legislative intent to give priority attention to chemicals which could have particularly harmful effects.

EPA's failure to respond to any of the ITC recommendations on testing priorities is currently being addressed in the courts. As part of this proceeding, the Assistant Administrator, OPTS, stated that EPA will now issue an ANPRM to satisfy the legal requirement that a rulemaking procedure be initiated within 1 year. However, the time needed to issue an ANPRM will still exceed the 1-year limit.

We did not assess the appropriateness of current test rule procedures but share EPA's concern about the time it has taken to issue test rules. EPA is now actively reviewing its test rule development process. Preliminary decisions have been made, and the staff is working on a proposal to streamline the current process.

CHAPTER 4

NEW CHEMICALS ARE BEING SCREENED, BUT MORE NEEDS TO BE DONE

A unique feature of TSCA is that, for the first time, the Government will be able to take action on potentially hazardous chemicals before damage occurs. Despite the fact that the chemical inventory, which triggered the act's premanufacture notice requirements, had been published more than 19 months late, EPA was not prepared to implement a PMN review program on July 1, 1979. Specifically, EPA did not have in place implementing regulations, a formal process for reviewing PMNs, or criteria to determine what action to take on the chemicals being reviewed because EPA has been unable to resolve basic issues.

REQUIREMENT FOR IDENTIFYING HAZARDOUS CHEMICALS BEFORE MANUFACTURE

The Congress recognized that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before production begins. Therefore, TSCA required that, beginning 30 days after publication of the chemical inventory, anyone intending to manufacture or import a new chemical substance must notify EPA at least 90 days before such manufacture or processing begins. Along with the notice, submitters must provide the following information:

--The common or trade name; the chemical identity and molecular structure; estimated production amounts; proposed use categories; methods of disposal; workplace exposure levels; and a description of byproducts, impurities, and other related products.

--Any test data related to the effect of the chemical substance on health or the environment in the possession or control of the person giving such notice.

--A description of any other data concerning the health and environmental effects of the substance, insofar as is known or reasonably ascertainable.

Additional information must be submitted if the chemical is subject to a test rule or is listed by EPA as a chemical which may present an unreasonable risk to health or the environment (commonly referred to as the "risk list").

EPA has 90 days--or 180 days if extended for good cause--to review this information and take appropriate action. Actions EPA can take include the following:

--If it is determined that insufficient information is available to evaluate the health and environmental effects of the substance and if, in the absence of this information, it is determined that the chemical may present an unreasonable risk of injury or that there may be significant or substantial human exposure, EPA can halt or limit its manufacture, processing, distribution in commerce, use, or disposal pending development of such information.

--If it is determined that the chemical substance will present an unreasonable risk of injury to health or the environment, EPA can take immediate action to limit exposure to the substance.

PMN PROGRAM NEEDS IMPROVEMENT

EPA's program to control new chemicals has been slow to develop. Although the existing chemical inventory was published more than 19 months after the date prescribed in the law, EPA was still not in a position to fully implement the PMN program. As of July 1980, EPA still has not

--issued final implementing regulations,

--developed strategies to implement all TSCA authorities affecting new chemicals, and

--established operating procedures or criteria to determine what action to take on a chemical.

PMN program operating under interim guidance pending final rules

In December 1977 a project manager was selected to develop an approach to and methodology for premanufacture notification. On January 10, 1979, EPA proposed for comment rules and notice forms to implement the PMN review program for new chemicals.

Based on concerns raised by commenters during the public comment period, EPA decided to repropose the PMN notice forms and certain other provisions of this proposal. Since the final PMN rules would not be in place when the notice requirement became effective on July 1, 1979, EPA issued, on May 15, 1979, an interim policy to be followed pending publication of the final PMN rules and forms.

The interim policy provided only limited guidance on who must report, what should be reported, and how confidential information would be handled. Basically, it required manufacturers and importers to submit that information specifically called for under TSCA as described above. In addition, it stated that the information submitted could be designated as confidential business information but strongly urged that confidentiality claims related to the specific chemical identity and health and safety data be substantiated.

According to a February 25, 1980, letter to a chemical manufacturer, the Deputy Assistant Administrator for Chemical Control characterized this level of reporting as follows:

> "* * * such minimal submissions still will lack much of the data and other information that EPA needs to conduct a reasonably sound assessment of your new chemical substances to determine whether they present potential risks to health or the environment."

On October 16, 1979, EPA reproposed for public comment a shorter PMN form, a clarification of its supplemental reporting requirements, and a significantly expanded requirement for substantiating confidentiality claims when the PMN is submitted. Although EPA expects to issue final PMN rules by December 1980, the Director of the Premanufacturing Review Division anticipates that the rule will be litigated. Based on his experience in such cases, he said that a suit could take as much as 2 or 3 years to resolve.

EPA must use all TSCA authority to obtain needed information

Information or data on new chemicals must be available to adequately perform risk assessments. Under the interim policy, EPA has not been receiving adequate toxicity or exposure data in PMN submissions. Therefore, as a matter of course, every manufacturer has been requested to submit additional information. In a March 1980 letter to the Chairman, Subcommittee on Environmental Pollution, Senate Committee on Environment and Public Works, the Administrator stated that:

"* * * Most companies have been willing to provide more information if it is readily available. However, few have been willing to generate additional information if to do so they would incur any significant expenditure of time and resources."

The lack of adequate information was emphasized by the Assistant Administrator, OPTS, in a January 5, 1980, speech before the American Association for the Advancement of Sciences. He stated:

"From EPA's perspective, however, by far the most disturbing result observed to date concerns the general lack of toxicity testing data submitted with notices on new chemicals. In fact, very little health and environmental effects testing has been performed on the new chemicals brought to EPA's attention thus far . . . virtually all of which involve some degree of human or environmental exposure. Not one notice contained chronic testing data. Twenty-one of the 35 notices contained no toxicity data at all. Most of the testing performed on the rest involved acute toxicity and eye/skin irritation. Only four notices included the results of mutagenicity screening tests; two, environmental effects data; and one, subacute toxicity data."

* * * * *

"If these early 'facts' indicate a trend, then--unless the situation is corrected--our review of notices will be based upon a <u>fundamental lack of information and data</u>. * * *" (Underscoring added.)

As shown in the table at the top of page 39, many of the notices still do not contain toxicity data. However, EPA does not believe that any of the 82 chemicals which have been reviewed as of July 16, 1980, pose a risk to health or the environment.

Toxicity Data Submitted with Premanufacture Notices Received through July 16, 1980 (199 Notices)

	Number of premanufacture notices	Percentage of total notices
Acute toxicity	80	40
Mutagenicity	45	23
No toxicity data submitted	120	60
Physical/chemical properties	103	52
No data submitted	31	15

The Assistant Administrator, OPTS, in a June 20, 1980, memorandum said that

> "* * * The situation may be helped some when the final PMN regulations are promulgated later this year. Nevertheless, we are unlikely to get in a PMN the amount or quality of information we would like to have in order to adequately review the chemical's possible risk."

However, EPA has not adequately considered how other TSCA provisions dealing with new chemicals could be used to obtain more information. Although EPA cannot require testing just because a chemical is new, TSCA does provide for submission of additional information, including test data, if the chemical is subject to a test rule or is on the section 5(b)(4) "risk list." In addition, if the information submitted is insufficient to determine the chemical's potential risk and the Administrator determines that the chemical may present an unreasonable risk or that there may be significant or substantial human exposure, EPA can take action under section 5(e) to regulate the chemical until adequate test data is submitted. EPA has not developed a strategy for implementing any of these provisions.

In April 1980 EPA issued its first order prohibiting the manufacture of six new chemicals on the grounds that they may pose serious risks to human health and the environment. The ban was to remain in effect until the manufacturer submitted additional test data or other information showing that the chemicals would not cause serious harm. Instead, the manufacturer withdrew the PMN.

The problem of not receiving adequate information in the PMNs was discussed at the December 1979 senior management retreat. As a result of this meeting, a task was initiated

to develop a strategy to induce industry to include more information, particularly test data, in the notices. The task was to focus on several legal authorities, including test rules for new chemicals, premanufacture testing guidelines, and the "risk list." Although work was started on this task, the current status is uncertain. EPA officials told us in June 1980 that because of the recent proposed reorganization and management changes, work on the task has stopped.

Need to establish operating procedures and decision criteria

Reviewing PMNs within the 90-day statutory time period will be difficult. In fact, current plans show that 180 days will be required for a complete review of a small number of potentially harmful chemicals. To assure that EPA's review process operates efficiently and that key decisions affecting the disposition of notices are consistent, EPA needs to establish (1) operating procedures covering all work phases and (2) decision criteria for determining what actions to take on the chemical.

Currently, the PMN review program is operating under draft procedures. EPA officials said that these procedures were developed without benefit of practical experience and therefore need to be updated based on the experience gained in reviewing PMNs submitted under the interim program. This is particularly important since as many as nine branches in seven divisions and offices within OPTS are involved, to some extent, in reviewing PMNs, which are expected to reach 1,000 annually by fiscal year 1982.

The current notice review is performed in two phases--initial screen and detailed review. At the end of the initial screen, a decision must be made on which notices to drop and which to assess in depth. The detailed review phase will require a decision on whether to drop, refer to other agencies or EPA offices, followup on, request more information on, or control the chemical. However, no formal criteria have been established to help make these decisions and to assure their consistency. According to the DAA for Chemical Control, decisions are now being made on a case-by-case basis.

The Chief, Notice Review Branch said, in June 1980 that the absence of decision criteria has affected the Branch's ability to review new chemicals. Without criteria to help determine which chemicals to eliminate after a cursory review, all chemicals are subject to the same review procedures. Thus, the Branch is not effectively using its resources.

Two OPTS staff members were assigned the task of developing decision criteria for the notice review program in March 1980. The staff member in charge told us in June 1980 that work has stopped on this effort due to the recent proposed reorganization and staff changes. No indication was given as to when, or if, the project will be completed.

ISSUES WHICH MUST BE RESOLVED

Two major, controversial issues surrounding the development of regulations to implement the PMN program are

--how much information is needed to adequately review new chemical substances within the 90-day review period and

--the confidentiality of the reported information.

Need for information versus impact on industry

If the potential risks associated with the manufacture, processing, distribution in commerce, use, or disposal of new chemical substances are to be assessed before manufacturing begins, EPA must have adequate data to assess this risk within the 90-day review period. However, the act cautions EPA to exercise its authority "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." Balancing these two competing objectives has caused much of the controversy in EPA's initial attempts to develop the implementing regulations.

The January 10, 1979, proposed PMN form required the reporting of information EPA believed necessary to evaluate the risks of new chemicals. Parts I and II of the proposed form required the submission of the specific information listed in the act (section 8(a)(2)) plus other information on the properties and effects of the substance which the submitter has evaluated, information related to human exposure and environmental release at the manufacturing and processing sites, and general population exposures that may result from use of products containing the chemical substance. Part III requested information--not mandatory--on other factors which can affect the magnitude of human and environmental risks from chemicals or influence the analysis of risk. EPA estimated the cost of completing all mandatory parts of the form to range from $3,700 to $22,200. Providing the optional data would add from $5,500 to $19,200.

Public interest organizations, other Federal agencies, and organized labor generally supported this proposed form. However, individual companies and trade associations commented that the information requirements were excessive both in scope and detail. Several industry commenters believed EPA went beyond the intent of the Congress and that the proposed approach would significantly impede innovation in the chemical industry.

In an attempt to reduce the economic burden on submitters, EPA shortened the form in its October 16 reproposal. According to EPA, the revised form would obtain adequate information to permit at least a preliminary assessment of the risks of new chemical substances. However, EPA stated that in some cases the information may be inadequate to fully determine how or if such substances should be regulated. The estimated cost to complete the revised form ranged from $1,200 to $8,900 per chemical, excluding the costs related to asserting and substantiating claims of confidentiality.

If the information submitted is inadequate to determine whether the chemical substance should be tested or otherwise controlled, EPA proposed using the act's section 8(a) authority to obtain supplemental information during the 90-day review period. Under this approach, EPA would provide a written notice to the submitter requesting the needed information. The submitter would then have 10 days to ask for clarification or modification. EPA believes that the use of this supplemental reporting authority is valid and necessary and is an integral part of EPA's reproposal to reduce the initial reporting burden and yet provide adequate information for the assessment process.

Public interest organizations as well as industry representatives object to this approach but for different reasons. Environmentalists believe that more information, not less, should be submitted with the PMN. In addition, the Natural Resources Defense Council said:

> "Adoption of the restricted PMN form proposed in October would effectively foreclose any possibility of adequately screening new chemicals. To ameliorate this fundamental flaw in the PMN, EPA is proposing to rely on a system of supplemental reporting. This approach threatens to turn the PMN process into a hugely burdensome yet ultimately unrewarding enterprise."

Industry commenters, on the other hand, raised questions concerning EPA's authority to require information through letterwriting rather than case-by-case rulemaking

procedures. Specifically, they said that EPA has circumvented the TSCA procedures for taking action when the information submitted is inadequate.

Protecting confidential business information while at the same time assuring meaningful public disclosure

TSCA does not prohibit the disclosure of health and safety studies or data disclosed to, or obtained by, EPA from a health and safety study relating to a chemical for which a PMN is required. Only the release of data which discloses processes used in the manufacture or processing of the substance or data disclosing the portion of the chemical substance in a mixture is excluded from disclosure.

Under the January 10, 1979, proposed PMN rule, submitters could assert a claim of confidentiality for any item of information provided. Only claims related to the specific chemical identity and information contained in a health and safety study had to be substantiated. Public interest groups commented that all claims of confidentiality should be substantiated when made. They argued that the proposed procedure would effectively preclude the release, during the 90-day review period, of information not warranting confidential treatment. An EPA official told us that, under the best of circumstances, EPA would need at least 70 days to get the submitter to substantiate a confidentiality claim and then rule on its merits. He said that, more than likely, information would not be released within the 90-day review period.

An alternative procedure was outlined in the October 16, 1979, reproposal in which all claims of confidentiality would be substantiated at the time a PMN is submitted. This revision, according to EPA, was made because of its experience to date with PMNs, comments received on the January 10 proposal, and further consideration of the various interested parties. Manufacturers submitting PMNs have claimed as confidential business information the following:

Confidentiality Claims
on Premanufacture Notices Received
through July 16, 1980 (183 Notices)

	Number of premanufacture notices	Percentage of total notices
Company name	109	59
Chemical identity	123	70
Use	96	52
Production volume	81	44
Health and/or safety data	33	a/19
Physical and/or chemical properties	41	a/22
No claims submitted	16	9

a/Understated. Not all notices contained this information.

Industry groups are opposed to substantiating claims of confidentiality in the PMN. Citing EPA contractor estimates that this requirement could add as much as $6,400 to the cost of completing the notice form, they argued that this would place an unnecessary burden on the submitter which could affect chemical innovation. In addition, they question EPA's authority to require upfront substantiation.

Probably the key confidentiality issue, according to the Director, Premanufacturing Review Division, is whether the specific chemical identity, or information which may disclose the identity, should be released with the health and safety study. The Environmental Defense Fund, an environmental interest group, in its comments on the January 10 proposal stated:

> "In the absence of identity, one cannot discern structure-activity relationships; assess the appropriateness of the tests and test methods used, given the characteristics of the substance; replicate the test, or conduct additional testing. The inability to evaluate the potential health and environmental effects of new chemicals in the manner just described deprives the public of its right to know the impact of such chemicals and reduces the role of public oversight of the premanufacture notification program to mere observation. * * *"

EPA agrees that the specific chemical identity may be the most important piece of information for judging a substance' possible health and environmental effects and that it generally considers the specific chemical identity to be part of a health and safety study. However, EPA proposes to deny a request for the specific chemical identity before manufacture or import because of what it believes to be the Congress' intent and other considerations. The January 10 proposal stated, in part:

> "* * * In particular, Section 5(d)(2) of the Act unmistakably provides that the notice of receipt of a premanufacture notice is to identify the chemical by generic name unless the Administrator determines that more specific indentification is required in the public interest. Congress, accordingly, seemed to recognize the importance of confidentiality prior to manufacture of a chemical for commercial purposes. * * *"
>
> * * * * *
>
> "A variety of policy considerations reinforce the idea that premanufacture confidentiality for chemical identities was intended by Congress. * * *"

CONCLUSIONS

As with most of other TSCA provisions, EPA has not implemented the PMN requirement of TSCA in a timely manner. Although the PMN program became effective in July 1979, the timely resolution of major issues has delayed issuance of the implementing regulations. Until final regulations are issued--now scheduled for December 1980--the PMN review program will operate under interim guidance.

From an operational standpoint, EPA must still develop procedures for reviewing new chemicals within the 90-day review period and establish decision criteria so that actions taken with respect to new chemicals are consistent and defensible. EPA is now developing review procedures, but it is not actively working on establishing decision criteria.

Even if the review process and decision criteria are in place, some question exists as to whether EPA will receive adequate data in the PMNs to assess the chemical's risk. Experience to date indicates that EPA may not receive adequate toxicity and exposure data. Unless this situation is corrected, EPA will be hamstrung in performing its reviews.

In our opinion, it is too early to determine whether the new chemical review program will be effective in preventing harmful chemicals from entering into commerce. First, EPA has not issued final PMN rules and forms; these should result in more information being submitted. Second, EPA has not fully considered how other TSCA provisions related to new chemicals could be used to encourage or require the submission of additional data, particularly test data.

RECOMMENDATIONS

We recommend that the Administrator, EPA, resume work on projects to

--develop a strategy to obtain needed information on new chemicals using all TSCA authorities and

--establish evaluation criteria for each decision point in the premanufacture review process.

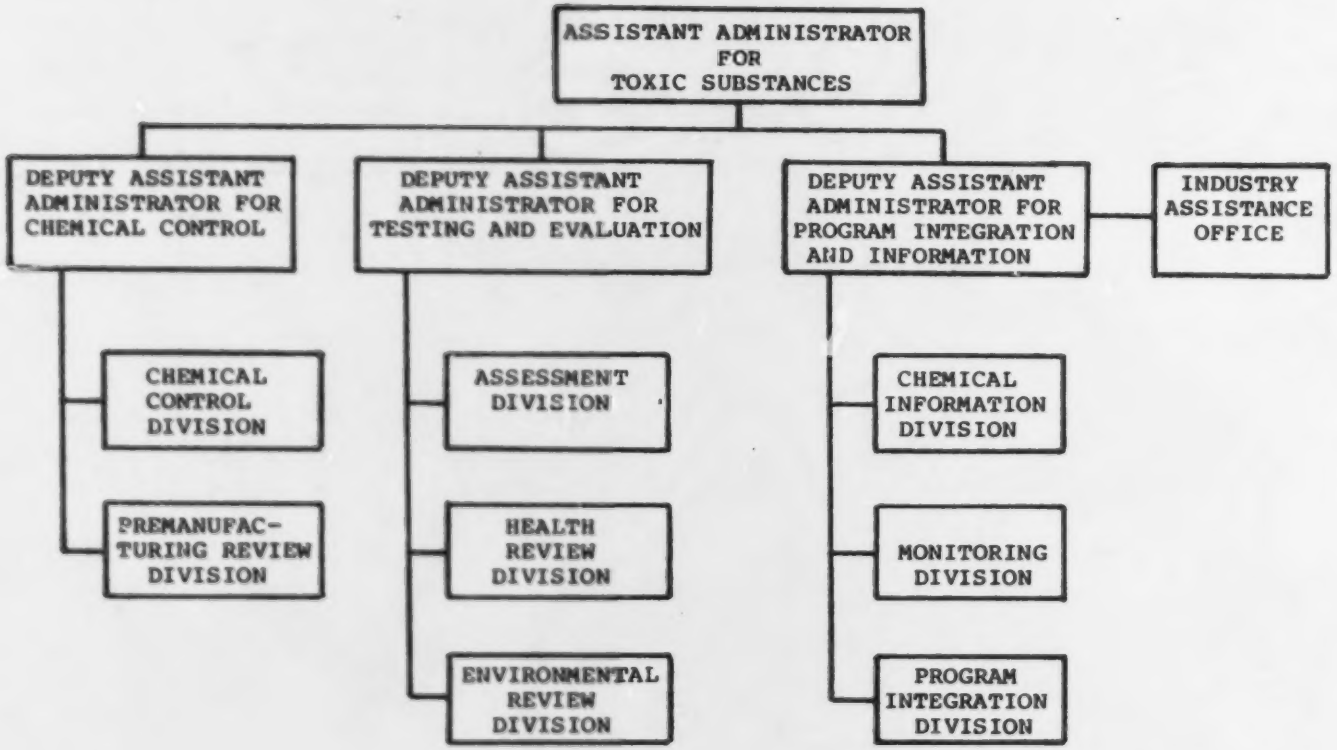
AGENCY COMMENTS

EPA commented (see app. III) that work is progressing on developing a strategy to obtain more information on new chemicals than is, in general, being provided with PMNs. A strategy options paper was prepared, and a task group charged with developing a strategy will review the options and make appropriate recommendations.

EPA commented that it does not now believe that decision criteria for determining unreasonable risk under premanufacture review or elsewhere in the statute are advisable. We recognize the difficulties in establishing criteria for unreasonable risk, and our recommendation is not directed toward having EPA develop rigid criteria for determining whether a chemical presents an unreasonable risk. Our recommendation, however, is directed to developing and formalizing evaluation criteria for such factors as chemical properties, exposure, etc., for each decision point in the PMN review process. Such criteria would help decisionmakers identify those chemicals warranting more in-depth assessment. We have modified our recommendation to clarify this point. In discussions subsequent to receiving EPA's comments, the Special Assistant to the Assistant Administrator, OPTS, agreed with our recommendation, as clarified, and said that such criteria will be developed.

ORGANIZATIONAL STRUCTURE

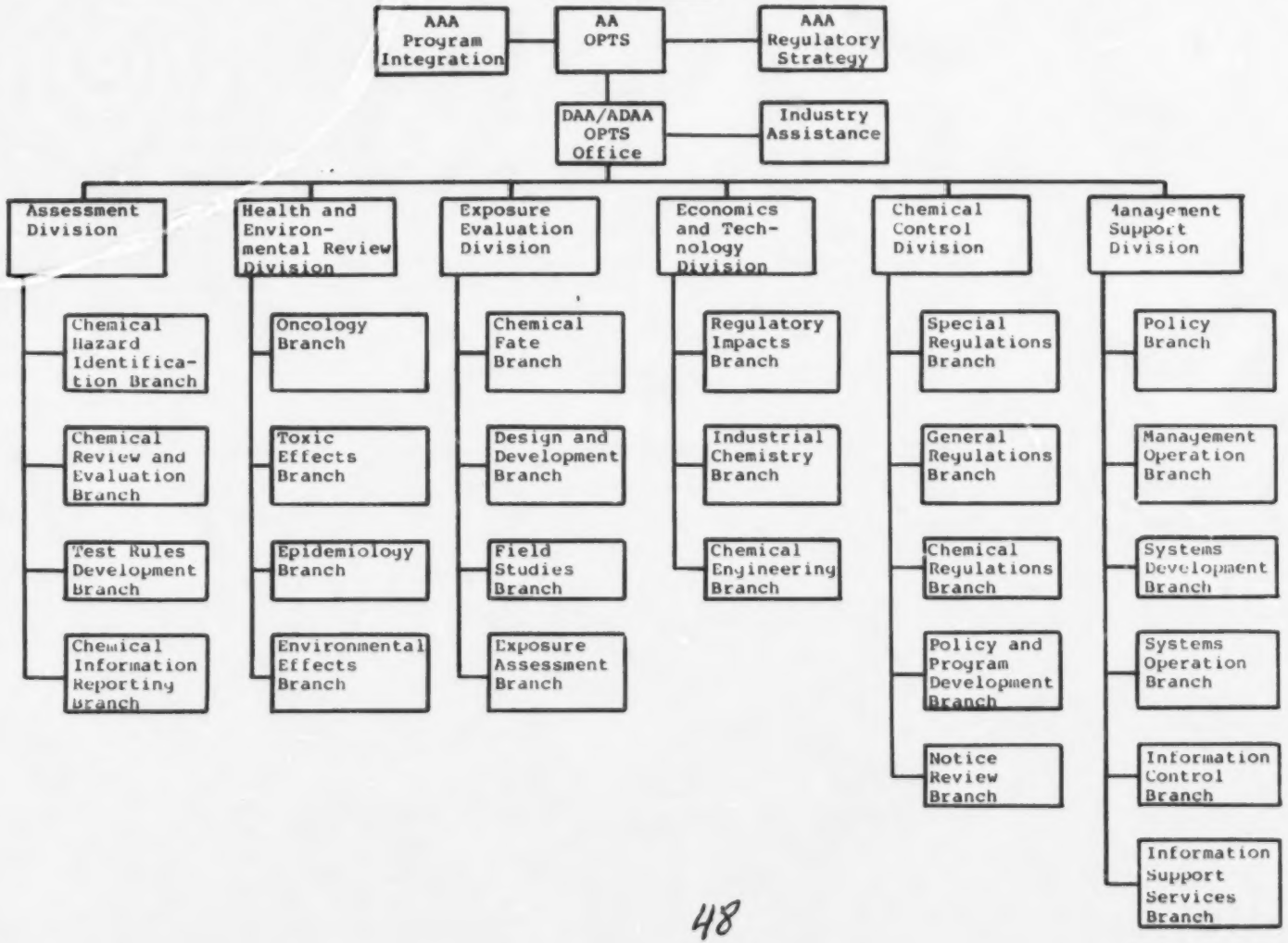
(MARCH 27, 1978, TO PRESENT)



APPENDIX I

PROPOSED REORGANIZATIONAL STRUCTURE

(MARCH 1980)



APPENDIX II

APPENDIX III

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 8 1980

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Community & Economic Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft report entitled "Slow Progress Characterizes EPA's Toxic Program." In general we found the report to be a fair summary of EPA's experience in implementing the Toxic Substances Control Act. We appreciate GAO's recognition of the fact that this is a particularly complicated piece of legislation to administer and that we have already taken actions to correct most of the problems they identified as interfering with the smooth implementation of the program in its early years. Because some of these changes are just beginning to bear fruit, the GAO review team was not able to observe how much better the program is now operating. We are enclosing a list of our recent and soon-to-be-achieved accomplishments to document this progress (Enclosure 1). If the Federal employment freeze is lifted . . . . reasonably soon and we are not seriously affected by the budget cuts, I fully expect this trend to continue.

The Agency would also like to comment briefly on the recommendations made at the conclusion of the report and offer some additional clarifying information.

GAO Recommendation

EPA should resume work on projects to develop a strategy to obtain needed information on new chemicals using all TSCA authorities.

EPA Response

Work is progressing on the development of a strategy to obtain more information on new chemicals than is, in general, being provided with premanufacture notices. The Office of

APPENDIX III

Toxic Substances staff recently prepared a paper outlining strategy options, a copy of which is enclosed for your information (Enclosure 2).[See GAO note.] The task group charged with developing a strategy for obtaining additional data will review the options and recommend a strategy for approval.

GAO Recommendation

EPA should resume work on projects to establish decision criteria for the premanufacture review process.

EPA Response

EPA does not now believe that decision criteria for unreasonable risk for disposition of chemicals under premanufacture review and elsewhere in the statute are advisable. Experience in attempting to develop these criteria has revealed the enormous difficulty in establishing criteria that adequately consider the many parameters involved in assessing a chemical. On the other hand, the development of more simplistic criteria, that would result in more cases of exception than application, does not make much sense. The case-by-case review procedure currently in effect is, in our opinion, a practical and effective means of evaluating the information contained in premanufacture notices for new chemicals. We therefore are approaching this issue basically from a performance criteria (i.e., does the situation potentially present an unreasonable risk) rather than a design criteria perspective which would have rigidly applicable triggers.

Although we are not attempting to establish specific decision criteria, we will continue to develop general guidance to assure efficient and consistent decision-making in the premanufacture review process. We have already developed and documented guidance to deal with a number of premanufacture issues, such as: (1) evaluation of the risks presented by new substances relative to the risks presented by existing substances for which they would substitute; (2) decisions to control new substances which are members of an existing family, when the family is not subject to control; and (3) decisions to control new substances causing particularly adverse effects, when we have not already controlled other existing substances which cause the same adverse effects. As we gain more experience with the premanufacture review process, we will develop similar guidance to deal with all major aspects of premanufacture decision-making.

GAO Note: Enclosures 2 through 4 have been deleted from this report.

APPENDIX III

Additional Technical and Clarifying Information

Section 8(a) Rules (p.22). The discussion of promulgation of section 8(a) rules should be updated. The Level B rule will be proposed during FY 81. Development of the Level C rule will be taken up after proposal of the Level B rule. These rules, when promulgated, will be model rules; future section 8(a) rule-making activities would involve only the addition of other chemicals with a short notice and comment period.

Section 4 Test Rules (p.31). Since the GAO report was drafted, two test rules and an exemption from testing have been proposed. On July 18, 1980, EPA published in the Federal Register a proposed test rule for the chemical chloromethane, a proposed test rule for the chemical category, chlorinated benzenes, and a proposed exemption from testing requirements for acrylamide. A copy of this notice is enclosed (Enclosure 3).

Other Control Actions (p. 31). In addition to those actions discussed by GAO, it should be noted that proposal of the Chemical Hazard Warning Label rule in the Federal Register is imminent. This action, being taken under section 6 of TSCA, is described in greater detail in enclosure 4.

Information Received with PMN's (p. 39). The table on page 39 tends to create the impression that a great deal of data is submitted with premanufacture notices. This is not, as GAO indicates and we agree, the case. Perhaps the chart should be reformatted.

[GAO Comment: Additional data was obtained from EPA and the table revised accordingly.]

We appreciate the opportunity to comment on the draft report.

Sincerely yours,

William Drayton, Jr.
Assistant Administrator
for Planning and Management

Enclosures

GAO Note: Page numbers have been changed to conform to the final version of the report.

APPENDIX III

ATTACHMENT 1

MAJOR TSCA OUTPUTS AS OF JULY 1980

Last 6 months

-- Issued cumulative supplement to Inventory, bringing total number of substances to nearly 55,000

-- All inventory plus production site and volume information not claimed confidential by submitter went on-line in computerized system available to each of EPA's Regional Offices

-- December 1979, proposed "model" section 8(d) rule that would gather unpublished studies on 61 chemicals and categories, including all priority testing recommendations received to date from TSCA section 4(e) Interagency Testing Committee as well as asbestos, benzidene-based dyes, styrene, dioxins, and chemicals used as solvents

-- February 1980, proposed section 8(a) rule to require that manufacturers submit basic information on how and to what extent people/environment exposed to some 2,200 chemicals (many among Nation's largest-volume substances)

-- July 1980, proposed rule under section 8(c) to establish mechanism for alerting corporate, labor, and government officials to potential chemical health and environmental problems in the workplace; rule would require any company to maintain records of allegations of significant adverse reactions caused by a chemical--from employees for 30 years and all others for 5 years--and to report these allegations to EPA upon request

-- Proposed first section 4 test rule in July 1980 (applies to 7 substances)

-- Issues proposed and final section 6(d) "immediately effective" rules in spring 1980 to prohibit transfer for disposal of dioxin-contaminated wastes

-- April 1980, issued first section 5(e) order to prohibit manufacture of six new chemicals (plasticizers)

-- Proposed regulations to prohibit PCB containing equipment from animal feedlots and fertilizer facilities

Next 6 months (and beyond)

-- CFC II rule (limit on CFC production) expected by March 1981 (proposal)

-- School asbestos rule for marking and inspection expected next month (proposal)

-- Acute hazard warning labels are scheduled to be proposed in the fall

-- Cancer hazard warning labels are expected to be proposed in the fall

APPENDIX III

-- Section 8(a) followup rule to require reports on chemicals that have passed through the PMN process will be proposed by the end of this year.

-- Three premanufacture notices are undergoing detailed assessment at this time in preparation for issuing proposed orders under section 5(e)

-- Twenty-eight new chemical substances, that have already completed the premanufacture notification period, have been identified as candidates for significant new use rules under section 5(a)(2). The first of these rules will be published in October 1980

-- The section 8(a) level A (preliminary assessment) reporting rule will be promulgated by the end of this year

-- The model section 8(d) rule will be promulgated and issued this fall

-- A proposed rule for the first section 4 environmental test standards will be published within the next few weeks (in Administrator's Office now for signature)

-- Subsequent environmental test standards to be proposed in batches of 2-10 beginning in March 1981

-- Proposed and final health test standards to be issued in spring 1981

-- A reimbursement rule for test data will be proposed by the end of December 1980

-- Final PMN rules/forms due to be issued in December 1980

-- Final section 12(b) export notification rule expected this fall

-- Proposal of commercial/industrial asbestos rule expected by spring of 1981

-- The second section 4 test rule, covering nitrobenzene, dichloromethane, 1,1,1-trichloroethane will be proposed in April 1981

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